

HOUSE BILL 818

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By: **Delegates Kipke and Hammen**

Introduced and read first time: February 11, 2011

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Manufacturers of Prescribed Products – Payments to Health Care**
3 **Professionals – Prohibition**

4 FOR the purpose of prohibiting a manufacturer of certain prescribed products from
5 offering or giving a gift to a health care professional; authorizing exceptions
6 from the prohibition for certain samples, loans of medical devices, articles or
7 journals, scholarships or other support, payments for certain conferences or
8 seminars, honoraria and payment of expenses, costs of certain clinical trials and
9 research projects, payments for certain scientific consulting, payment or
10 reimbursement for certain technical training, royalties, and licensing fees, and
11 donated health care products, under certain circumstances; authorizing the
12 Department of Health and Mental Hygiene to adopt certain regulations;
13 defining certain terms; and generally relating to payments to health care
14 professionals from manufacturers of prescribed products.

15 BY adding to

16 Article – Health – General

17 Section 21–228

18 Annotated Code of Maryland

19 (2009 Replacement Volume and 2010 Supplement)

20 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
21 MARYLAND, That the Laws of Maryland read as follows:

22 **Article – Health – General**

23 **21–228.**

24 **(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE**
25 **MEANINGS INDICATED.**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **(2) “BONA FIDE CLINICAL TRIAL” MEANS A CLINICAL TRIAL**
2 **REVIEWED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT:**

3 **(I) CONSTITUTES “RESEARCH” AS THAT TERM IS DEFINED**
4 **IN 45 C.F.R. § 46.102; AND**

5 **(II) REASONABLY CAN BE CONSIDERED TO BE OF INTEREST**
6 **TO SCIENTISTS OR HEALTH CARE PROFESSIONALS WORKING IN THE**
7 **PARTICULAR FIELD OF INQUIRY.**

8 **(3) “CLINICAL TRIAL” MEANS A STUDY:**

9 **(I) ASSESSING THE SAFETY OR EFFICACY OF PRESCRIBED**
10 **PRODUCTS ADMINISTERED ALONE OR IN COMBINATION WITH OTHER**
11 **PRESCRIBED PRODUCTS OR OTHER THERAPIES; OR**

12 **(II) ASSESSING THE RELATIVE SAFETY OR EFFICACY OF**
13 **PRESCRIBED PRODUCTS IN COMPARISON WITH OTHER PRESCRIBED PRODUCTS**
14 **OR OTHER THERAPIES.**

15 **(4) “GIFT” MEANS ANY PAYMENT, FOOD, ENTERTAINMENT,**
16 **TRAVEL, SUBSCRIPTION, ADVANCE, SERVICE, OR ANYTHING ELSE OF VALUE**
17 **PROVIDED TO A HEALTH CARE PROFESSIONAL, UNLESS THE HEALTH CARE**
18 **PROFESSIONAL REIMBURSES THE COST AT FAIR MARKET VALUE.**

19 **(5) (I) “HEALTH CARE PROFESSIONAL” MEANS:**

20 1. **AN INDIVIDUAL WHO IS:**

21 **A. LICENSED OR CERTIFIED UNDER THE HEALTH**
22 **OCCUPATIONS ARTICLE; AND**

23 **B. AUTHORIZED TO PRESCRIBE OR RECOMMEND**
24 **PRESCRIBED PRODUCTS;**

25 2. **A PARTNERSHIP OR CORPORATION COMPOSED OF**
26 **THE INDIVIDUALS DESCRIBED IN ITEM 1 OF THIS SUBPARAGRAPH; OR**

27 3. **AN OFFICER, EMPLOYEE, AGENT, OR**
28 **CONTRACTOR OF A PERSON DESCRIBED IN ITEM 1 OR 2 OF THIS SUBPARAGRAPH**
29 **WHO IS ACTING IN THE COURSE AND SCOPE OF EMPLOYMENT OR A CONTRACT**
30 **RELATED TO OR SUPPORTIVE OF THE PROVISION OF HEALTH CARE TO**
31 **INDIVIDUALS.**

1 (II) "HEALTH CARE PROFESSIONAL" DOES NOT INCLUDE AN
2 INDIVIDUAL EMPLOYED SOLELY BY A MANUFACTURER.

3 (6) (I) "MANUFACTURER" MEANS:

4 1. A PHARMACEUTICAL, BIOLOGICAL PRODUCT, OR
5 MEDICAL DEVICE MANUFACTURER; OR

6 2. ANY OTHER PERSON THAT IS ENGAGED IN THE
7 PRODUCTION, PREPARATION, PROPAGATION, COMPOUNDING, PROCESSING,
8 PACKAGING, REPACKAGING, DISTRIBUTING, OR LABELING OF PRESCRIBED
9 PRODUCTS.

10 (II) "MANUFACTURER" INCLUDES A WHOLESALE
11 DISTRIBUTOR THAT HOLDS A PERMIT UNDER TITLE 12, SUBTITLE 6C OF THE
12 HEALTH OCCUPATIONS ARTICLE.

13 (III) "MANUFACTURER" DOES NOT INCLUDE A PHARMACIST
14 LICENSED UNDER TITLE 12, SUBTITLE 3 OF THE HEALTH OCCUPATIONS
15 ARTICLE.

16 (7) "MARKETING" MEANS PROMOTION, DETAILING, OR ANY
17 OTHER ACTIVITY THAT IS INTENDED TO BE USED OR IS USED TO INFLUENCE
18 SALES OR MARKET SHARE OF A PRESCRIBED PRODUCT.

19 (8) "PRESCRIBED PRODUCT" MEANS:

20 (I) A DRUG OR DEVICE AS DEFINED IN § 201 OF THE
21 FEDERAL FOOD, DRUG, AND COSMETIC ACT; OR

22 (II) A BIOLOGICAL PRODUCT AS DEFINED IN § 351 OF THE
23 FEDERAL PUBLIC HEALTH SERVICE ACT.

24 (9) "SIGNIFICANT EDUCATIONAL, SCIENTIFIC, OR POLICY
25 CONFERENCE OR SEMINAR" MEANS AN EDUCATIONAL, SCIENTIFIC, OR POLICY
26 CONFERENCE OR SEMINAR THAT:

27 (I) IS OFFERED BY AN ENTITY ACCREDITED BY THE
28 ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION OR A
29 COMPARABLE ORGANIZATION; AND

30 (II) 1. OFFERS CONTINUING MEDICAL EDUCATION
31 CREDIT;

1 **2. FEATURES MULTIPLE PRESENTERS ON**
2 **SCIENTIFIC RESEARCH; OR**

3 **3. IS AUTHORIZED BY THE SPONSORING**
4 **ASSOCIATION TO RECOMMEND OR MAKE POLICY.**

5 **(B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A**
6 **MANUFACTURER MAY NOT OFFER OR GIVE ANY GIFT TO A HEALTH CARE**
7 **PROFESSIONAL.**

8 **(C) THE PROHIBITION UNDER SUBSECTION (B) OF THIS SECTION DOES**
9 **NOT APPLY TO:**

10 **(1) SAMPLES OF A PRESCRIBED PRODUCT PROVIDED TO A**
11 **HEALTH CARE PROFESSIONAL FOR FREE DISTRIBUTION TO PATIENTS;**

12 **(2) THE LOAN OF A MEDICAL DEVICE FOR A SHORT-TERM TRIAL**
13 **PERIOD, NOT TO EXCEED 180 DAYS, TO PERMIT EVALUATION OF THE MEDICAL**
14 **DEVICE BY A HEALTH CARE PROFESSIONAL OR PATIENT;**

15 **(3) THE PROVISION, DISTRIBUTION, DISSEMINATION, OR RECEIPT**
16 **OF PEER-REVIEWED ACADEMIC, SCIENTIFIC, OR CLINICAL ARTICLES OR**
17 **JOURNALS AND OTHER ITEMS THAT SERVE A GENUINE EDUCATIONAL FUNCTION**
18 **PROVIDED TO A HEALTH CARE PROFESSIONAL FOR THE BENEFIT OF PATIENTS;**

19 **(4) A SCHOLARSHIP OR OTHER SUPPORT FOR MEDICAL**
20 **STUDENTS, RESIDENTS, AND FELLOWS TO ATTEND A SIGNIFICANT**
21 **EDUCATIONAL, SCIENTIFIC, OR POLICY CONFERENCE OR SEMINAR OF A**
22 **NATIONAL, REGIONAL, OR SPECIALTY MEDICAL OR OTHER PROFESSIONAL**
23 **ASSOCIATION;**

24 **(5) PAYMENT TO THE SPONSOR OF A SIGNIFICANT EDUCATIONAL,**
25 **SCIENTIFIC, OR POLICY CONFERENCE OR SEMINAR, IF:**

26 **(I) THE PAYMENT IS NOT MADE DIRECTLY TO A HEALTH**
27 **CARE PROFESSIONAL;**

28 **(II) THE PAYMENT IS USED SOLELY FOR BONA FIDE**
29 **EDUCATIONAL PURPOSES; AND**

30 **(III) ALL PROGRAM CONTENT IS OBJECTIVE AND FREE FROM**
31 **INDUSTRY CONTROL, AND THE CONTENT DOES NOT PROMOTE SPECIFIC**
32 **PRESCRIBED PRODUCTS;**

1 **(6) PAYMENT FOR A GOVERNMENT-SPONSORED EDUCATIONAL,**
2 **SCIENTIFIC, OR POLICY CONFERENCE OR SEMINAR, IF:**

3 **(I) THE CONFERENCE OR SEMINAR IS SPONSORED BY A**
4 **FEDERAL, STATE, OR LOCAL GOVERNMENT AGENCY FOR THE PURPOSE OF**
5 **DEVELOPING, IMPLEMENTING, OR EVALUATING GOVERNMENT POLICY;**

6 **(II) THE PAYMENT IS USED SOLELY TO UNDERWRITE THE**
7 **CONFERENCE OR SEMINAR EXPENSES; AND**

8 **(III) ALL PROGRAM CONTENT IS OBJECTIVE AND FREE FROM**
9 **INDUSTRY CONTROL, AND THE CONTENT DOES NOT PROMOTE SPECIFIC**
10 **PRESCRIBED PRODUCTS;**

11 **(7) HONORARIA AND PAYMENT OF THE EXPENSES OF A HEALTH**
12 **CARE PROFESSIONAL WHO SERVES ON THE FACULTY AT A SIGNIFICANT**
13 **EDUCATIONAL, SCIENTIFIC, OR POLICY CONFERENCE OR SEMINAR, IF:**

14 **(I) THERE IS AN EXPLICIT CONTRACT WITH SPECIFIC**
15 **DELIVERABLES THAT ARE RESTRICTED TO EDUCATIONAL, SCIENTIFIC, POLICY,**
16 **OR MEDICAL ISSUES AND DO NOT INCLUDE MARKETING ACTIVITIES; AND**

17 **(II) THE CONTENT OF THE PRESENTATION, INCLUDING**
18 **SLIDES AND WRITTEN MATERIALS, IS DETERMINED BY THE HEALTH CARE**
19 **PROFESSIONAL;**

20 **(8) DIRECT AND INDIRECT COSTS OF A BONA FIDE CLINICAL**
21 **TRIAL, INCLUDING:**

22 **(I) DIRECT SALARY SUPPORT OF THE PRINCIPAL**
23 **INVESTIGATOR AND OTHER HEALTH CARE PROFESSIONALS; AND**

24 **(II) EXPENSES PAID ON BEHALF OF INVESTIGATORS OR**
25 **OTHER HEALTH CARE PROFESSIONALS PAID TO REVIEW THE CLINICAL TRIAL;**

26 **(9) DIRECT AND INDIRECT COSTS, INCLUDING DIRECT SALARY**
27 **SUPPORT AND NECESSARY EXPENSES, OF A RESEARCH PROJECT THAT:**

28 **(I) CONSTITUTES A SYSTEMATIC INVESTIGATION;**

29 **(II) IS DESIGNED TO DEVELOP OR CONTRIBUTE TO**
30 **GENERAL KNOWLEDGE; AND**

1 (III) REASONABLY CAN BE CONSIDERED TO BE OF
2 SIGNIFICANT INTEREST OR VALUE TO SCIENTISTS OR HEALTH CARE
3 PROFESSIONALS WORKING IN THE PARTICULAR FIELD OF INQUIRY;

4 (10) PAYMENT FOR BONA FIDE SCIENTIFIC CONSULTING, IF:

5 (i) THE CONSULTING IS GOVERNED BY A WRITTEN
6 AGREEMENT BETWEEN THE HEALTH CARE PROFESSIONAL AND THE
7 MANUFACTURER THAT SPECIFIES CLEAR AND SUBSTANTIVE DELIVERABLES ON
8 THE PART OF THE HEALTH CARE PROFESSIONAL;

9 (ii) THE PAYMENT TO THE HEALTH CARE PROFESSIONAL
10 CONSISTS SOLELY OF COMPENSATION AT FAIR MARKET VALUE AND
11 REIMBURSEMENT FOR THE REASONABLE EXPENSES, INCLUDING TRAVEL AND
12 LODGING, ASSOCIATED WITH THE BONA FIDE SCIENTIFIC CONSULTING WORK;

13 (iii) THE CONSULTING DOES NOT INCLUDE MARKETING
14 ACTIVITIES; AND

15 (iv) PAYMENT IS NOT BASED ON OR RELATED TO A DECISION
16 TO USE A PRESCRIBED PRODUCT;

17 (11) PAYMENT OR REIMBURSEMENT FOR THE REASONABLE
18 EXPENSES, INCLUDING TRAVEL AND LODGING, NECESSARY FOR TECHNICAL
19 TRAINING OF A HEALTH CARE PROFESSIONAL ON THE USE OF A MEDICAL
20 DEVICE, IF THE COMMITMENT TO PAY OR REIMBURSE THE EXPENSES AND THE
21 AMOUNTS OR CATEGORIES OF REASONABLE EXPENSES TO BE PAID OR
22 REIMBURSED ARE DESCRIBED IN A WRITTEN AGREEMENT BETWEEN THE
23 HEALTH CARE PROFESSIONAL AND THE MANUFACTURER;

24 (12) ROYALTIES AND LICENSING FEES PAID TO HEALTH CARE
25 PROFESSIONALS IN RETURN FOR CONTRACTUAL RIGHTS TO USE OR PURCHASE
26 A PATENTED OR OTHERWISE LEGALLY RECOGNIZED DISCOVERY FOR WHICH
27 THE HEALTH CARE PROFESSIONAL HOLDS AN OWNERSHIP RIGHT; AND

28 (13) HEALTH CARE PRODUCTS DONATED TO A PUBLIC OR PRIVATE
29 NONPROFIT EDUCATIONAL OR HEALTH CARE ORGANIZATION OR INSTITUTION
30 FOR TRAINING OR FREE DISTRIBUTION TO PATIENTS OR THE PUBLIC, IF THE
31 DONATION DOES NOT REQUIRE THE ORGANIZATION OR INSTITUTION TO
32 PURCHASE A PRESCRIBED PRODUCT.

33 (D) THE DEPARTMENT MAY ADOPT REGULATIONS TO CARRY OUT THIS
34 SECTION.

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
2 October 1, 2011.